



Bureau of HIV and STD Prevention

HIV/STD Clinical Resources Division
HIV/STD Epidemiology Division
HIV/STD Health Resources Division

Est. March 25, 1998

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HIV/STD Policy No. 220.101

PURCHASING PRESCRIPTION OR OVER-THE-COUNTER MEDICATIONS AND VITAMINS NOT COVERED BY A THIRD-PARTY PAYOR

PURPOSE

This policy provides guidance on the appropriate use of grant funds to purchase over-the-counter (OTC) medication when clients are not eligible for prescription medication services provided through third-party payors. Contracting agencies will be able to purchase prescription medication for clients: 1) who do not have or are not eligible for insurance, 2) when a prescription medication is not allowed under certain third-party payor criteria, and 3) to meet medication needs that are not met by other sources of funding. This policy is directed to contracting agencies providing HIV-related public health services whose activities allow for medication purchases (i.e., Ryan White Title II, state services, and early intervention programs). Application of this policy will assure that grant funds reimburse for medication only when no other parties will pay.

AUTHORITY

Ryan White CARE Act Amendments of 1996, Section 2616; Texas Dangerous Drug Act, V.T.C.A. Health and Safety Code, Chapter 483; Texas Administrative Code, Section 291.33, Class A Pharmacy Operational Standards; Texas Administrative Code, Section 291.93, Class D Pharmacy Operational Standards; Code of Federal Regulations, Title 21, Section 310.518, Drug Products Containing Iron or Iron Salts; HIV/STD Policy No. 220.100; HIV/STD Policy No. 540.001.

PROGRAM REQUIREMENTS

The Texas Department of Health (TDH) requires a consortium considering medication purchases to develop a formulary or designate a dollar amount per client based on client needs and budgeting caps. To assure the best use of grant funds, the need for medication purchases must be identified prior to budgeting. As with all budgeting, allocations are based upon needs identified in the local needs assessment.

When the need for a formulary has been identified, the TDH requires that the consortium form a three-member committee to be responsible for developing a formulary and budget. The committee must consist of a physician, pharmacist, and the executive director of the administrative agency. A nurse practitioner or physician's assistant who is working with the physician may represent the physician on the committee. Should the consortium be unable to fulfill the committee member requirements, substitutes must be approved by the HIV/STD Clinical Resources Division of the Bureau of HIV and STD Prevention.

1 It is the responsibility of the committee to decide the extent to which they will use the
2 grant funds, which are set aside by the consortium, to purchase medication for eligible
3 clients. The consortium should approve the final formulary and budget prior to
4 implementing, however, the consortium may not make any changes to the final
5 formulary submitted by the committee.

6 7 CLIENT ELIGIBILITY

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9 Clients who qualify for prescription medication services provided through third-party
10 payors such as health insurance, Medicaid, the HIV/STD Medication Program, indigent
11 health care, or the HIV Health Options to Promote Employment (HOPE) Program are
12 not eligible to receive services directed through this policy. Purchasing of medication
13 listed on the HIV/STD Medication Program formulary for clients eligible to receive third-
14 party reimbursable services is covered under the provisions of HIV/STD Policy No.
15 220.100. Clients unable to meet co-pay requirements should request assistance
16 through their local Ryan White Insurance Program or apply to the HIV HOPE Program
17 administered by the TDH.

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19 When a purchase of a prescription medication is not allowed under certain third-party
20 payor criteria and the client is without means to pay for the prescription medication, the
21 client is eligible to receive prescription medication services, provided funds are
22 available. To receive assistance, the client must provide documentation to the
23 contracting agency that the third-party payor does not cover the requested medication.

24 25 PRESCRIPTION MEDICATION

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27 Only licensed practitioners (i.e., pharmacists, physicians, nurses, dentists, and
28 podiatrists) may dispense prescription medication. Prescription medication may not be
29 budgeted as food pantry purchases. Agencies may purchase medication through the
30 HIV/STD Medication Program (Medication Plus Program). For more information
31 regarding the Medication Plus Program, contact the HIV/STD Medication Program at 1-
32 800-255-1090. Another alternative for purchasing medication is to establish a cost
33 reimbursement system with pharmacies licensed to distribute medications in Texas.
34 Funds may not be used to make direct payments of cash to a client.

35
36 Employees, board members, clients, or volunteers of an agency are restricted from
37 collecting and/or dispensing prescriptions, or prescription medication except when
38 working under the provision of a license issued by the Texas State Board of Pharmacy.
39 Agencies that stock, collect, or dispense any prescription medication without physician
40 orders or who interfere with the legal dispensing of prescription medications will be in
41 violation of this policy and be subject to contract termination. Violations of State
42 pharmaceutical laws will be reported to the proper authorities.

OVER-THE-COUNTER MEDICATION AND VITAMINS

Facilities may provide OTC medication only when the medication is approved by the Food and Drug Administration (FDA), sealed by the manufacturer, and not past the expiration date. Vitamins may be provided when they are sealed by the manufacturer. These items should be stored in a restricted, non-client flow area, which is locked when unattended. Vitamins containing iron must have a child-proof cap. No partially used or opened containers may be passed on to others. Employees and volunteers who are not licensed practitioners of facilities that stock vitamins and OTC medication should not physically hand these items out to clients. Under these circumstances, clients should be allowed to choose and remove vitamins and OTC medication from the shelf themselves. Clinicians may provide OTC medication and vitamins with appropriate client consultation and education.

Facilities providing OTC medication and/or vitamins will post appropriate bilingual signs stating at least the following:

“Please talk with your doctor, nurse, or pharmacist about possible side effects before taking any over-the-counter medication or vitamin.”

CLINICAL TRIALS

HIV service funds awarded through TDH may not be used to support the costs of operating clinical trials of investigational agents or treatments (to include administrative management or medical monitoring of patients). Funds may, however, be used to promote enrollment in clinical trials as part of broader outreach activities or to support clinical costs of expanded access or compassionate use programs where efficacy data exist and where the FDA has authorized such expanded use.

Expanded Access Programs - created by the FDA for the purpose of making promising new treatments available to persons with life-threatening diseases and with no other treatment options.

Compassionate Use Programs - programs sponsored by pharmaceutical companies to make investigational new medications available for the same group of persons described in expanded access programs.

COMPLIANCE MONITORING

The HIV/STD Clinical Resources Division and Field Operations Branch staff will work together to verify compliance of this policy during site visits. Contracting agencies that violate this policy will face administrative sanctions, up to and including termination of

1 their contract. Refer to HIV/STD Policy No. 540.001 for information relating to
2 sanctions imposed upon contractors for noncompliance.

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4 DATE OF LAST REVIEW:

5 November 13, 2002 Converted format from WordPerfect to Word.

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7 REVISIONS

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9 Page 1, line 27 Changed "HIV/STD Clinical Services Section" to "HIV/STD Clinical
10 Resources Division"

11 Page 3, line 14 Changed "HIV/STD Clinical Services Section" to "HIV/STD Clinical
12 Resources Division"